

REMARKS

Claims 18-21, 25-29, 38 and 39 have been amended. Claims 18-21, 25-29, and 39 have been amended to delete the recitation "dermopharmaceutical". Claim 18 has also been amended to recite "consisting essentially of" to exclude any additional ingredients that would have altered the basic and novel characteristics of the invention. Claim 38 has also been amended to further define the recited variables R1, R2, and X, the support for which can be found in original claim 1. Claim 39 has also been amended to delete the recitation of "prevention" from the claim. Claims 22, 24, 30-37, and 40 have been withdrawn as being drawn to a non-elected invention. No new matter has been added. Thus, entry of the amendment is respectfully requested.

Election/Restriction:

Having elected the claims of Group I and the species of octopamine, claims 18-21, 25-29, 38, 39, and 41 are now under examination.

35 U.S.C. § 112, First Paragraph:

Claim 39 has been rejected for lack of enablement under 35 U.S.C. § 112, first paragraph. In the Patent Office's view, the specification does not provide enablement for the prevention of melanin production, because the claims are overly broad insofar as "they suggest that melanin production will not occur when taking the claimed material; or that following treatment with this compound, it will not recur." While Applicant does not agree with the Patent Office's position, solely to expedite prosecution, Applicant has deleted the recitation of "prevention" from claim 39. Accordingly, Applicant requests withdrawal of the rejection.

35 U.S.C. § 112, Second Paragraph:

Claims 18-21, 25-29, 38, 39, and 41 have been rejected as being indefinite under 35 U.S.C. § 112, second paragraph.

The Office has taken the position that "dermopharmaceutical" requires certain activity, the scope of which is unclear, "as the specification only discloses the activity of skin lightening, i.e., the reduction in melanin production." While Applicant strongly disagrees, solely to expedite prosecution, Applicant has deleted the recitation "dermopharmaceutical". Accordingly, withdrawal is requested.

In addition, the Patent Office has taken the position that claim 18, which recites both an excipient and an acid "acceptable in cosmetic terms" is unclear. As a helpful suggestion, the Examiner has recommended that Applicant amend the claim to recite "a cosmetically acceptable" excipient or acid. While we are willing to amend the claim to any term that is clear, definite, and of identical scope as the claim language, Applicant submits that there is no *ipsis verbis* support in the specification for the Examiner's recommendation. Of course, we agree with the Examiner that the proposed language is synonymous with the recitation of the claim. Should the Examiner wish to discuss this term, he should feel free to contact the undersigned.

With respect to the excipient, solely to expedite prosecution, Applicant has amended the claim to delete the offending language. With respect to the "acid acceptable in cosmetic terms", Applicant submits that the specification provides explicit support for the recitation "acid acceptable in cosmetic terms" at paragraph [0023], for example. Thus, the claim is of clear and definite scope, such that a skilled artisan could readily determine the full scope of the claim. Accordingly, Applicant requests withdrawal of the rejection.

Furthermore, the Patent Office has rejected claim 38 for being indefinite, as the variables: R1, R2, and X of the general formula (I), are not defined by the claim. For clarity, Applicant has amended the claim to recite the missing variables.

Accordingly, Applicant requests withdrawal.

35 U.S.C. § 102:

Claims 18-21, 25-29, 38, 39, and 41 have been rejected as being anticipated under 35 U.S.C. § 102, by Satoh *et al.* [European Patent Application 0189681]. According to the Patent Office, Satoh discloses a composition that comprises 6.7 wt% of octopamine hydrochloride salt along with other ingredients [see page 21, Example 46]. As the rejection is applied to the claims, as amended Applicant respectfully traverses.

Satoh, *et al.* teaches a transdermal therapeutic preparation for introducing an ionic water-soluble medicine through the corneal layers of the epidermis and into the circulatory system. Satoh *et al.*'s invention requires (1) an absorption accelerator and (2) an ionic water-soluble medicine, such as octopamine, for example. Applicants have amended claim 18 directed to a cosmetic to recite "consisting essentially of", which is meant to have excluded any additional ingredients that would have altered the basic and novel characteristics of the cosmetic invention, such as Satoh's absorption accelerator. Combining octopamine with a compound that directs the medication out of the skin and into the circulatory system would be contrary to the claimed invention because combining octopamine with such other substances would alter the basic and novel characteristics of the cosmetic. The present invention is formulated to act directly on the skin to reduce melanogenesis and to remain on the skin. By its very nature, Satoh's transdermal therapeutic invention is formulated to penetrate through the skin and into the circulatory system, which is contrary to the claimed invention. Accordingly, withdrawal of the rejection is requested.

In addition, claim 38 has also been rejected as being anticipated by Satoh *et al.* In the Patent Office's view, despite the fact that "Satoh *et al.* does not disclose how the

octopamine employed was prepared", claim 38 is a product claim and, thus, is anticipated by the teachings in *Satoh et al.* Applicant respectfully traverses.

The Federal Circuit has recently decided that for infringement purposes, the claims are limited to the methods they recite. *Abbott Labs. v. Sandoz, Inc.* 566 F.3d 1282, 1293 (Fed. Cir. 2009) (*en banc*). A courtesy copy of the case is attached as Exhibit A. Specifically, the court pronounced:

Thus, based on Supreme Court precedent and the treatment of product-by-process claims throughout the years by the PTO and other binding court decisions, this court now restates that "process terms in product-by-process claims serve as limitations in determining infringement." *Atl. Thermoplastics*, 970 F.2d at 846-47. As noted earlier, this holding follows this court's clear statement in *In re Thorpe* that "product by process claims are limited by and defined by the process." 777 F.2d at 697.

Id. (emphasis added).

While it is understood that the Patent Office is charged with giving a claim its broadest reasonable interpretation, in view of *Abbott Labs.*, the broadest reasonable interpretation of a product-by-process claim is limited by the process terms it recites. Applicant submits that it is unreasonable to have claims interpreted in different ways—one way for infringement and one way for patentability. Thus, broadly construed, the method limitations of claim 38 should be interpreted as limitations, *per se*, which as acknowledged by the Office, are not taught by the cited reference. Thus, claim 38 is not anticipated by *Satoh et al.*, and accordingly, withdrawal is requested.

Lastly, claim 39 has been rejected as being anticipated by *Satoh et al.* The Patent Office has taken the

position that the recitation "further comprising one material for the prevention or reduction of melanin production" is anticipated by Satoh *et al.*, since the reference discloses a formula comprising octopamine which is a material for the prevention or reduction of melanin production. Applicant respectfully traverses.

Claim 39 as drafted requires the composition of claim 18 plus an additional element of "at least one material for the reduction of melanin production" that is not taught by Satoh *et al.*, inherently or otherwise. The claim recitation "further comprising at least one material for the reduction of melanin production" is properly interpreted to require that an additional element be physically present. Satoh *et al.* does not teach a compound comprising, for example, octopamine and, in addition, a material for the reduction of melanin production to be added to the composition. Accordingly, claim 39 is not anticipated by Satoh and withdrawal of the rejection is requested.

In the event any fee is due in connection with the present response, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: August 27, 2009

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